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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,749	12/08/2003	David Angelo Tomasso	CDS-0290	2640

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EXAMINER	
LEVKOVICH, NATALIA A	
ART UNIT	PAPER NUMBER
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,749	TOMASSO ET AL.	
	Examiner	Art Unit	
	Natalia Levkovich	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *15-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 30-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-14 and 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the 'test element recess for holding one or more test elements or test element holders, wherein the removable holder is configured to contain the test element recess such that a test element can be acted upon by the liquid dispense or aspirating station, while the test element is in the recess'.

The limitation is unclear because the configuration of the 'test elements', or 'test element holders' is not defined, and, therefore, it is not clear what structural features of the 'removable holder' would provide for the above-cited functionality, as well as it is not clear whether or not the configuration of the 'removable holder' adapted for holding test elements, is different from the one adapted for 'test element holders'. It is also unclear how the 'removable holder' of lines 5 and 9 is related to the holder of line 4. Applicant is advised to use consistent terminology.

In claim 2, the 'sample sample reservoir' lacks antecedent basis. Is it the same as the 'fluid supply section for holding a sample' of claim 1? See also claim 4.

Claim 30 recites a 'veterinary analyzer comprising an analyzer according to claim 1 and a T4 assay'. It is unclear what structural features of the device recited in claim 1 limit the device to being specifically 'veterinary' and configured for T4 assay.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 10-11 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Clark et al. (US 6190617).

Clark discloses an automated analyzer comprising, as shown in Figure 4A, concentrically arranged carousels 36 ("reagent vessel carousel") and 32 ("reagent pack carousel") - ['transport system', 'first and second rotors' – Ex.] and stationary probe 6 ['liquid dispense or aspirating station' – Ex.]. The carouses carry various types of 'removable holders', such as, for example, holder illustrated in Figures 36-42, which accommodate vessels capable of containing samples or reagents ['fluid supply sections for holding a sample', 'sample reservoirs', or 'test elements' – Ex.]. Figures 36 and 40 show holders having recesses capable of holding probe tips ['probe tip dispenser' – Ex.], as well as sample tubes ['test elements' – Ex.]. The holders arrange the items on the 'same line of travel' intersecting the stationary probe.

The system also includes 'measurement devices', such as modules 69, 71 and photomultiplier tube which measure the chemiluminescent signal of the samples (see Figures 16 and 17).

Referring to claim 5, Clark teaches that "the reaction vessel containing the test sample and one or more reagents is transferred to a process carousel wherein controlled environment conditions exist ['incubator' – Ex"] (Col.16, lines 5-10).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al.

In reference to claim 30, although Clark does not specify the intended use of the apparatus as a veterinary one specifically configured for T4 assay, such analyzers are

common are well known. It would have been within the ordinary skill of an artisan at the time the invention was made to have employed the apparatus of Clark for conducting routine T4 assays for animal biological fluids.

Regarding claim 31, Clark does not teach the analyzer sized to be employed as a desktop device. However, multiple carousel desktop analyzers are very well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Clark such as to reduce its dimensions to a desktop sizes, in order to enhance the scope of applicability of the apparatus.

8. Claim 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. in view of Long (US 5219526).

Clark does not teach test strips / 'dry slide test elements'. However, these test elements are well known for a long time and are routinely employed in the art (see, for example, dry test pad 74 in Figure 3 of Long). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed these test elements in the modified the apparatus of Clark, in order to enhance the scope of applicability of the apparatus.

Allowable Subject Matter

9. Claims 7-9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art does not teach, or fairly suggest waste collection containers and centrifuge modules 'removably' located on the rotors.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-14 and 30-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7

and 24-26 of co-pending Application No 10/436,537. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the instant claims are entirely within the scope of the co-pending application. The instant claims are encompassed by the claims of 10/436,537.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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